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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,161	BENJAMIN ET AL.	
	Examiner	Art Unit	
	CARLIC K. HUYNH	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 35-38* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16,17 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on November 16, 2007 is acknowledged.

Status of the Claims

1. Claims 1-17 and 35-38 are pending in the application, with claim 15 having been withdrawn in response to the restriction requirement submitted on October 20, 2006. Accordingly, claims 1-14, 16-17, and 35-38 are being examined on the merits herein.

Response to Arguments

2. Claim 15 is withdrawn because the claim is not directed to the elected compound of 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino)-3-cyano-7-ethoxy-quinolin-6-yl]-amide. In order for 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino)-3-cyano-7-ethoxy-quinolin-6-yl]-amide to meet the compound of the formula in claim 15, X would need to be a phenyl substituted with **two** halogens. However, X in claim 15 is a phenyl optionally substituted with **a halogen**. Given the broadest interpretation of claim 15, X is a phenyl that can be substituted with **a halogen** and **not** two halogens. Thus, claim 15 is properly withdrawn as not being directed to Applicants' election of the species 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino)-3-cyano-7-ethoxy-quinolin-6-yl]-amide. Applicants' election was made without traverse in the reply filed on November 2, 2006.

Claims 1-14, 16-17, and 35-38 are directed to a stabilized pharmaceutical composition and thus intended use is not given any patentable weight.

Examiner's Response to Previously Presented Arguments

3. Applicants argue "previously pending objections and rejections are deemed withdrawn" from the Office Action dated July 27, 2007. "However, the Examiner has issued a new set of rejections presented in this Office Action, several of which rejections are based on the very same references as the original set of rejections. Applicants refer to MPEP 707.07(g), which states in part:

> 'Piecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available, avoiding, however, undue multiplication of references."'

Response to Arguments

4. In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Moreover, Applicants further state "all valid and available grounds for objection/ rejection were *not* presented in the first Office Action". As such, the Office Action dated on July 27, 2007 was issued to address the "grounds for objection/ rejection were *not* presented in the first Office Action".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-14, 16-17, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabindran et al. (US 6,617,333).

Rabindran et al. teaches an EKB-569 composition (abstract). The tablet formulations may be made by wet granulation or dry granulation and utilize pharmaceutically acceptable diluents, binding agents, lubricants, disintegrants, surface modifying agents, and suspending or stabilizing agents including calcium carbonate (column 7, lines 17-20 and 26). It is noted that the chemical formula for EKB-569 is known in the art as 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino-3-cyano-7-ethoxy-quinolin-6-yl]amide (column 1, lines 13-15). Oral formulations may utilize standard delay or time release formulations to alter the absorption of EKB-569 (column 7, lines 36-37).

Regarding the amounts of the pH of the composition, as recited in claims 4-6 and 37, it is noted that Rabindran et al. teach various pharmaceutically acceptable excipients including calcium carbonate (column 7, line 26). Since Rabindran et al. teach calcium carbonate, it would be obvious that the EKB-569 composition may be basic and thus have a pH of at least 8, which closely meets the amounts of pH set forth in claims 4-6 and 37. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of calcium carbonate provided in a composition, according to the

guidance set forth in Rabindran et al., to provide a composition having desired pH. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the amounts of the weights of the basic excipients in the pharmaceutical composition, as recited in claims 7-9, it is noted that Rabindran et al. teach providing calcium carbonate (column 7, line 26). Since Rabindran et al. teach calcium carbonate, it would be obvious that the EKB-569 composition contain calcium carbonate that is about 0.1% to about 50% by weight of the pharmaceutical composition, which closely meets the weights of the basic excipients in the pharmaceutical composition set forth in claims 7-9. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of calcium carbonate provided in a composition, according to the guidance set forth in Rabindran et al., to provide a composition having desired weight of the basic excipient in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding immediate release and sustained release pharmaceutical compositions as recited in claims 12 and 13, respectively, it is noted that Rabindran et al. teach oral formulations may utilize standard delay or time release formulations to alter the absorption of EKB-569 (column 7, lines 36-37). Since Rabindran et al. teach oral formulations may utilize standard delay or time release formulations to alter the absorption of EKB-569, it would be obvious that

the EKB-569 pharmaceutical compositions of Rabindran et al. may be an immediate release form or a sustained release form.

Regarding enteric coated pharmaceutical compositions as recited in claim 14, it is noted that Rabindran et al. teach various pharmaceutically acceptable ingredients (column 7, lines 19-21). Since Rabindran et al. teach various pharmaceutically acceptable ingredients, it would be obvious that the EKB-569 pharmaceutical compositions of Rabindran et al. may be enteric coated.

Response to Arguments

6. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on November 16, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 1-14, 16-17, and 35-38 have been fully considered and are not persuasive. Applicant argues that Rabindran et al. (US 6,617,333) do not teach a concentration of calcium carbonate needed to achieve a particular pH (e.g. a pH of 8 or more). In response, Examiner points out that Rabindran et al. teach a number of suspending or stabilizing agents including calcium carbonate (column 7, lines 17-20 and 26). The composition of Rabindran et al. thus may contain calcium carbonate and because the composition contains calcium carbonate, the concentration of calcium carbonate can be adjusted to any value in order to attain a pH of 8 or more. Thus, the Rejections under 35 U.S.C. § 103 to claims 1-14, 16-17, and 35-38 have been maintained.

7. Claims 1-14, 16-17, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masferrer (US 2004/0127470).

Masferrer teaches EKB-569 (abstract and page 62, table 10). It is noted that the chemical formula for EKB-569 is known in the art as 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino-3-cyano-7-ethoxy-quinolin-6-yl]amide. The composition of EKB-569 is made into tablets and can contain calcium carbonate (pages 82-83, paragraph [1209]). Masferrer also teaches art acceptable methods of drug formulation (page 82, paragraph [1206]).

Masferrer further teaches that the pharmaceutical composition is can contain a controlled-release formulation, which is provided by hydroxypropylmethyl cellulose, and additionally be prepared with enteric coatings (pages 82-83, paragraph [1209]). The composition can be combined with one or more adjuvants (pages 82-83, paragraph [1209]).

Regarding the amounts of the pH of the composition, as recited in claims 4-6 and 37, it is noted that Masferrer teaches calcium carbonate (pages 82-83, paragraph [1209]). Since Masferrer teaches calcium carbonate, it would be obvious that the EKB-569 composition may be basic and thus have a pH of at least 8, which closely meets the amounts of pH set forth in claims 4-6 and 37. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of calcium carbonate provided in a composition, according to the guidance set forth in Masferrer, to provide a composition having desired pH. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the amounts of the weights of the basic excipients in the pharmaceutical composition, as recited in claims 7-9, it is noted that Masferrer teaches calcium carbonate (pages 82-83, paragraph [1209]). Since Masferrer teaches calcium carbonate, it would be obvious that

the EKB-569 composition contain calcium carbonate that is about 0.1% to about 50% by weight of the pharmaceutical composition, which closely meets the weights of the basic excipients in the pharmaceutical composition set forth in claims 7-9. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of calcium carbonate provided in a composition, according to the guidance set forth in Masferrer, to provide a composition having desired weight of the basic excipient in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding immediate release pharmaceutical compositions as recited in claims 12, it is noted that Masferrer teaches the pharmaceutical composition is can contain a controlled-release formulation (pages 82-83, paragraph [1209]). Since Masferrer teaches oral formulations can contain a controlled-release formulation of EKB-569, it would be obvious that the EKB-569 pharmaceutical compositions of Masferrer can be an immediate release form.

Regarding wet or dry granulation as recited in claims 35-38, claims 35-38 are still rendered obvious over the teachings of Masferrer as product by process claims. Masferrer teaches tablets and art acceptable methods of drug formulation (pages 82-83, paragraphs [1206] and [1209]). It is well known that there are a number of processes that will yield tablets including dry granulation and wet granulation. Thus, it would be obvious that tablets are made by processes such as dry granulation or wet granulation. It is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

8. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on November 16, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 1-14, 16-17, and 35-38 have been fully considered and are not persuasive.

Applicant argues that "there is no guidance whatsoever in Masferrer describing a preferred or optimal pH level, and therefore there can be no motivation to vary or optimize the amount of calcium carbonate to achieve a particular pH level". Applicant further argues "there is no indication in Masferrer that calcium carbonate, even if included in a tablet with EKB-569, would be used for a purpose related to pH modification" and that in fact "Mansferrer teaches away from a high pH oral formulation in describing calcium carbonate as a 'buffer', since buffers are known in the art to *resist,* rather than cause, pH change".

In response, Examiner points out that Masferrer teach the composition of EKB-569 is made into tablets and can contain calcium carbonate (pages 82-83, paragraph [1209]). The composition of Masferrer thus may contain calcium carbonate and because the composition contains calcium carbonate, the concentration of calcium carbonate can be adjusted to any value in order to attain a pH of 8 or more.

Thus, the Rejections under 35 U.S.C. § 103 to claims 1-14, 16-17, and 35-38 have been withdrawn in light of the arguments.

9. Claims 1-14, 16-17, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wissner et al. (US 6,002,008) in view of Cotton et al. (International Journal of Pharmaceutics 1994, 109, 237-249).

Wissner et al. teach a compound of formula (I), namely 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino)-3-cyano-7-methoxy-quinolin-6-yl]amide (column 90, lines 24-26).

Wissner et al. also teach the compounds of the claimed invention may have solid carriers or excipients, including starch, lactose, dicalcium phosphate, microcrystalline cellulose, sucrose, and kaolin (column 41, lines 46-48).

Furthermore, Wissner et al. teach a solid dosage form (column 41, lines 57-60) and tablets (column 41, lines 10-15). The compounds of the invention may be administered in a sustained release form (column 41, line 33).

Wissner et al. teach 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino)-3-cyano-7-**methoxy**-quinolin-6-yl]amide, which is a structural homolog of the instantly claimed compound 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino-3-cyano-7-**ethoxy**-quinolin-6-yl]amide, i.e., they differ only by a CH_2 group. Thus, one having ordinary skill in the art would have been motivated to prepare the instantly claimed compound because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results. *In re Hass*, 60 USPQ 544 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950).

Wissner et al. do not teach basic excipients in the pharmaceutical composition and concentrations of basic excipients that are sufficient to bring the pH of the composition to at least 8.

Cotton et al. teach that basic excipients, e.g. glycine and sodium carbonate, may be used to stabilize and prevent the degradation of L-649,923, which is caused by the cyclization of its γ-hydroxy free acid. Cotton et al. also teach that an equivalent to 1.0 molar concentration of glycine brings the pH of the L-649,923 composition to 7.3 and that an equivalent to 0.5 molar concentration of sodium carbonate brings the pH of the L-649,923 composition to 9.5 (Table 6).

Regarding "basic exicipient" as recited in claims 1-6, 10-11, 16, and 35-38, it is noted the basic excipient is used to stabilize and prevent the degradation of the pharmaceutical composition caused by cyclization of the dimethylamino-but-2-enoic acid side chain (page 14, lines 1-2 of the specification).

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the pharmaceutical composition of Wissner et al. to contain a basic excipient because the basic excipient glycine or sodium carbonate of Cotton et al. can be used to stabilize and prevent the degradation of acidic groups of compositions and to bring the pH of those compositions to at least 8. Since Cotton et al. teaches that glycine or sodium carbonate can prevent the degradation of L-649,923 caused by the cyclization of its γ-hydroxy free acid, combining Cotton's glycine or sodium carbonate and Wissner's compositions would have reasonably been expected to be effective to stabilize and prevent the degradation of the methylamino-but-2-enoic acid side chain caused by its cyclization and to bring the pH of the composition to at least 8.

The motivation to combine the pharmaceutical composition of Wissner et al. to the basic excipient of Cotton et al. is that the compounds of Cotton et al. contain glycine or sodium carbonate and that such compositions can be used to stabilize and prevent the degradation of acidic groups of compositions and to bring the pH of those compositions to at least 8.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding the amounts of the pH of the composition, as recited in claims 4-6 and 37, it is noted that Cotton et al. teach providing glycine and sodium carbonate will yield a composition pH of 7.3 and 9.5, respectively, which closely meets the amounts of pH set forth in claims 4-6 and 37 (Table 6). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of glycine or sodium carbonate provided in a composition, according to the guidance set forth in Cotton et al., to provide a composition having desired pH. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the amounts of the weights of the basic excipients in the pharmaceutical composition, as recited in claims 7-9, it is noted that Cotton et al. teaches an equivalent to 1.0 molar concentration of glycine and an equivalent to 0.5 molar concentration of sodium

carbonate, which closely meets the weights of the basic excipients in the pharmaceutical composition set forth in claims 7-9 (Table 6). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of calcium carbonate provided in a composition, according to the guidance set forth in Cotton et al., to provide a composition having desired weight of the basic excipient in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding immediate release and enteric coated pharmaceutical compositions as recited in claims 12 and 14, respectively, it is noted that Wissner et al. teach formulations may be formulated neat or combined with one or more pharmaceutically acceptable carriers (column 41, lines 10-12). Since Wissner et al. teach formulations may be formulated neat or combined with one or more pharmaceutically acceptable carriers, it would be obvious that the 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino-3-cyano-7-**ethoxy**-quinolin-6-yl]amide pharmaceutical compositions of Wissner et al. may be an immediate release form or an enteric coated pharmaceutical composition.

Regarding wet or dry granulation as recited in claims 35-38, claims 35-38 are still rendered obvious over the teachings of Wissner et al. as product by process claims. Wissner et al. teaches oral formulations and tablets (column 41, lines 10-15). It is well known that there are a number of processes that will yield tablets including dry granulation and wet granulation. Thus, it would be obvious that tablets are made by processes such as dry granulation or wet granulation. It is noted that "[E]ven though product-by-process claims are limited by and

defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

10. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on November 16, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 1-14, 16-17, and 35-38 have been fully considered and are not persuasive.

Applicants argue that the methoxy homolog of the EKB-569 in Wissner et al. (US 6,002,008) is not equivalent to EKB-569 itself because the homologs do not possess "similar properties". Moreover, it is well known in the chemical arts that even small differences in chemical structure often result in profound chemical and biological differences.

In response, Examiner agrees that small differences in chemical structure often result in profound chemical and biological differences. However, Examiner points out that Wissner et al. teach 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino)-3-cyano-7-**methoxy**-quinolin-6-yl]amide, which is a structural homolog of the instantly claimed compound 4-dimethylamino-but-2-enoic acid [4-(3-chloro-4-fluoro-phenylamino-3-cyano-7-**ethoxy**-quinolin-6-yl]amide, i.e., they differ only by a CH_2 group. The differences is not a methoxy versus a ethoxy group but rather between a ethyl and a methyl group. Methyl and ethyl groups are known to possess similar properties. Thus, one having ordinary skill in the art would have

been motivated to prepare the instantly claimed compound because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results. *In re Hass*, 60 USPQ 544 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950).

Applicant further argues that "the sodium carbonate used in Cotton et al. (International Journal of Pharmaceutics 1994, 109, 237-249) is responsible for preventing cyclization of the gamma-hydroxy free acid side chain of L-649,923, there is absolutely no reason a skilled chemist would conclude that sodium carbonate would also prevent cyclization of a *completely dissimilar* dimethylamino-but-2-enoic side chain. The skilled chemist would immediately recognize that the respective side chains are of different lengths, possess different heteroatoms, possess different substituents, and possess different carbon-carbon bonding patterns".

In response, Examiner points out that Cotton et al. was solely used to demonstrate techniques known in the art to prevent the degradation of acid side chains with basic excipients such as sodium carbonate. The combination of the compounds of Wissner et al., which are the homologous compounds of EKB-569, and the teachings of Cotton et al. to prevent the degradation of compounds containing an acidic side chain with sodium carbonate meet the limitations of instant claims 1-14, 16-17, and 35-38.

Thus, the Rejections under 35 U.S.C. § 103 to claims 1-14, 16-17, and 35-38 have been withdrawn in light of the arguments.

Conclusion

11. No claims are allowable.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

ckh